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Dated: June 9, 2004

Signature: Sharon Ditch  
(Sharon Ditch)

Docket No.: HO-P02276US1  
(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Tibor Juhasz *et al.*

Application No.: 09/536,861

Art Unit: 3739

Filed: March 27, 2000

Examiner: D. Shay

For: **METHOD OF CORNEAL SURGERY BY  
LASER INCISING A CONTOURED  
CORNEAL FLAP**

### AMENDMENT UNDER 37 CFR § 1.114

MS RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

### INTRODUCTORY COMMENTS

In response to the Office Action dated December 9, 2003, finally rejecting claims 12-38, please amend the above-identified U.S. patent application as follows:

**Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.

**Remarks/Arguments** begin on page 6 of this paper.

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The inadequacy of the pulse energy required in Swinger/Lai has been shown by studies described in several articles. *See*, (1) A.J. Joglekar et.al., Optics at Critical Intensity: Applications to Nanomorphing, *Proceedings of the National Academy of Sciences*, vol. 101, p. 5856-5861, (2004); (2) A. P. Joglekar *et al.*, A Study of the Deterministic Character of Optical Damage by Femtosecond Laser Pulses and Applications to Nanomachining, *Applied Physics B*, vol. 77, p. 25-30. (2003). These articles show that the size of localized damage points can be as small as few hundred nanometers, and they do not result in separable cuts in the tissue. Moreover, due to their small and gentle effect, their practical applications are in cellular microsurgery, such as cutting genes inside cells. This is in contrast to the effect of pulses above the optimized pulse energy density where the photodisruption generates cavitation bubbles that are much larger in a way that they touch each other to provide clean and contiguous macroscopic level tissue resections as it was shown by (1) Ratkay-Traub et al and Nordan et.al., First Clinical Results with the Femtosecond Neodymium-glass Laser in Refractive Surgery, *Journal of Refractive Surgery*, vol.19, p.94-103 (2003); (2) L Nordan *et al.*, Femtosecond Laser Flap Creation for Laser *in situ* Keratomileusis: Six month follow up of initial U.S. clinical series. *Journal of Refractive Surgery*, vol. 19. p.8-14, (2003). The energy density or fluence used in the surgeries described by Ratkay-Traub and Nordan is in the range of 75 to 100 J/cm<sup>2</sup>, (75 to 100 microJoule/(10 micron)<sup>2</sup>) 75 to 100 J/cm<sup>2</sup>, (75 to 100 microJoule/(10 micron)<sup>2</sup>), that is 15 to 20 times larger than the upper limit (5 J/cm<sup>2</sup> (5 microJoule/(10 micron)<sup>2</sup>) given by Swinger-Lai. Copies of these articles are attached.

Independent claims 12 and 24 have been amended to recite that the pulsed laser beam has an optimized pulse energy density above a minimum level for achieving tissue modification. In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If there any questions, please call the undersigned at the telephone listed below.

Enclosed herewith is a check covering the RCE transmittal fee and the fee for a 3-month extension of time. Applicant believes no additional fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02276US1 from which the undersigned is authorized to draw.

Dated: June 9, 2004

Respectfully submitted,

By

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